REMARKS

Claims 9 and 10 have been canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claims in this or any other patent application. Accordingly, Claims 1-8 and 11-13 are presented for examination.

Correction of Inventorship under 37 CFR §1.48(b)

Applicant requests that several inventors be deleted, as these inventors' inventions are no longer being claimed in the present application as a result of prosecution. The fee as set forth in § 1.17(i) is submitted herewith.

Priority

The PTO has stated that because the claimed polypeptides have no utility, the priority under 35 U.S.C. § 120 is set at the instant filing date, May 2, 2002. Applicants have previously listed the priority information for the instant application in a Preliminary Amendment mailed September 3, 2002. The preliminary amendment states that the instant application is a continuation of, and claims priority under 35 U.S.C. § 120 to, US Application 10/006867 filed 12/6/2001, which is a continuation of, and claims priority under 35 U.S.C. § 120 to, PCT Application PCT/US00/23328 filed 8/24/2000, which is a continuation-in-part of, and claims priority under 35 U.S.C. § 120 to, US Application 09/380137 filed 8/25/1999, which is the National Stage filed under 35 U.S.C. § 371 of PCT Application PCT/US99/12252 filed 6/2/1999, which claims priority under 35 U.S.C. § 119 to US Provisional Application 60/090444 filed 6/24/1998.

Applicants submit that for the reasons stated below, the claimed polypeptides have a credible, substantial, and specific utility. The sequence of SEQ ID NO: 56 was first disclosed in Figure 2 of US Provisional Application 60/090444 filed 6/24/1998. The data in Example 18 (Tumor Versus Normal Differential Tissue Expression Distribution), relied on in part for the utility of the claimed polypeptides, were first disclosed in PCT Application PCT/US00/23328 filed 8/24/2000, on page 93, line 3, through page 96, line 35.

Information Disclosure Statement

The Examiner stated that an Information Disclosure Statement did not appear to have been submitted. Applicants note that an Information Disclosure Statement was submitted September 6, 2002 and a postcard confirming receipt by the PTO was received by the Applicants' representatives.

On the IDS submitted September 6, 2002 Applicants inadvertently listed U.S. Patent No. 5,546,637 rather than U.S. Patent No. 5,536,637. Accordingly, Applicants submit herewith an Information Disclosure Statement listing the references submitted in the IDS of September 6, 2002 and corrected for the typographical error in the listing of U.S. Patent No. 5,536,637.

Claim Objections

Claims 1-10 were objected to for reciting figure numbers. These claims have been amended to remove the figure numbers.

Claims 7-11 were objected to as being in improper dependent form for failing to further limit the subject matter of a previous claim. In particular, the Examiner asserts that these claims are redundant excerpts from parent Claim 6. Applicants maintain that the scope of Claim 6 is different from the scope of Claims 7-11 in that Claim 6 is a Markush claim encompassing a plurality of polypeptides while Claims 7-11 recite individual polypeptides which are encompassed within the group of polypeptides recited in Claims 7-11. Since the scope of Claim 6 is different than that of Claims 7-11, Applicants maintain that Claims 7-11 are not redundant.

Rejections Under 35 U.S.C. §101

The Examiner asserts that the claimed invention lacks a specific, substantial and credible utility. In particular, the Examiner asserts that the only disclosure of the structure of the protein is through generalities and that there is no disclosure of any relationship between the structure and function of the protein. The Examiner further asserts that there is no disclosure of any disease or condition in any way related to the claimed polypeptide nor is there disclosure of any diagnostic assay or analytical assay that could be performed using the claimed polypeptides. The Examiner also asserts that numerous other uses of the claimed polypeptides provided in the specification are insufficient to provide a specific, substantial and credible utility. In addition, the Examiner further asserts that the specification is unclear whether PRO1027 stimulates TNF-α

production in human blood and that, even if it does stimulate TNF-α production , this activity would not impart utility to the claimed polypeptides.

As discussed in more detail below, Applicants maintain that, as provided in Example 18 of the application, the polypeptide of SEQ ID NO: 56 is over-expressed in melanoma relative to normal skin and that this differential expression provides a specific, substantial and credible utility. Applicants note that PRO1027 is not among the proteins which stimulate TNF-α production in human blood.

Utility – Legal Standard

According to the Utility Examination Guidelines ("Utility Guidelines"), 66 Fed. Reg. 1092 (2001) an invention complies with the utility requirement of 35 U.S.C. § 101, if it has at least one asserted "specific, substantial, and credible utility" or a "well-established utility."

Under the Utility Guidelines, a utility is "specific" when it is particular to the subject matter claimed. For example, it is generally not enough to state that a nucleic acid is useful as a diagnostic tool without also identifying the condition that is to be diagnosed.

The requirement of "substantial utility" defines a "real world" use, and derives from the Supreme Court's holding in *Brenner v. Manson*, 383 U.S. 519, 534 (1966) stating that "The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." In explaining the "substantial utility" standard, M.P.E.P. § 2107.01 cautions, however, that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. "Rather, *any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient,* at least with regard to defining a 'substantial' utility." (M.P.E.P. § 2107.01, emphasis added.)

Indeed, the Guidelines for Examination of Applications for Compliance With the Utility Requirement, set forth in M.P.E.P. § 2107 II(B)(1) gives the following instruction to patent examiners: "If the applicant has asserted that the claimed invention is useful for any particular practical purpose ... and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility."

Utility – Evidentiary Standard

An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101, "unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope." *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). See, also *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (1965); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

Compliance with 35 U.S.C. § 101 is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) cert. denied, 469 US 835 (1984). The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, **the PTO must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility.** Only after the PTO has made a proper *prima facie* showing of lack of utility does the burden of rebuttal shift to the applicant. The issue will then be decided on the totality of evidence.

Substantial Utility

Applicants have established that the Gene Encoding the PRO1027 Polypeptide is Differentially Expressed in Certain Cancers compared to Normal Tissue and is Useful as a Diagnostic Tool

Example 18 demonstrates that the nucleic acid encoding PRO1027 is expressed at a higher level in melanoma than in normal tissue. Applicants maintain that this differential expression renders the claimed polypeptides useful in diagnosing or treating cancer.

As an initial matter, Applicants note that, although the PRO1027 protein is not one of the proteins which stimulated TNF-α production in human blood, the Examiner asserted that the demonstration of "higher" levels of TNF-α did not confer utility on the claimed polypeptides because it was unclear whether the "higher" levels were significantly higher.

Applicants submit herewith a copy of a declaration of J. Christopher Grimaldi, an expert in the field of cancer biology, originally submitted in a related co-pending and co-owned patent application Serial No. 10/063,557 (attached as Exhibit 1). In paragraph 5 of his declaration, Mr.

Grimaldi states that the gene expression studies reported in Example 18 of the instant application were made from pooled samples of normal and of tumor tissues. Mr. Grimaldi explains that:

> The DNA libraries used in the gene expression studies were made from pooled samples of normal and of tumor tissues. *Data from pooled samples is more likely to be accurate than data obtained from a sample from a single individual.* That is, the detection of variations in gene expression is likely to represent a more generally relevant condition when pooled samples from normal tissues are compared with pooled samples from tumors in the same tissue type. (Paragraph 5) (emphasis added).

In paragraphs 6 and 7, Mr. Grimaldi explains that the semi-quantitative analysis employed to generate the data of Example 18 is sufficient to determine if a gene is over- or underexpressed in tumor cells compared to corresponding normal tissue. He states that any visually detectable difference seen between two samples is indicative of at least a two-fold difference in cDNA between the tumor tissue and the counterpart normal tissue. He also states that the results of the gene expression studies indicate that the genes of interest "can be used to differentiate tumor from normal." He explains that, "The precise levels of gene expression are irrelevant; what matters is that there is a relative difference in expression between normal tissue and tumor tissue." (Paragraph 7). Thus, since it is the relative level of expression between normal tissue and suspected cancerous tissue that is important, the precise level of expression in normal tissue is irrelevant. Likewise, there is no need for quantitative data to compare the level of expression in normal and tumor tissue. As Mr. Grimaldi states, "If a difference is detected, this indicates that the gene and its corresponding polypeptide and antibodies against the polypeptide are useful for diagnostic purposes, to screen samples to differentiate between normal and tumor."

Applicants have established that the Accepted Understanding in the Art is that there is a Direct Correlation between mRNA Levels and the Level of Expression of the Encoded Protein

As stated above, the standard for utility is not absolute certainty, but rather whether one of skill in the art would be more likely than not to believe the asserted utility. Applicants submit herewith a copy of a second Declaration by J. Christopher Grimaldi, an expert in the field of cancer biology (attached as Exhibit 2). This declaration was submitted in connection with the related co-pending and co-owned application Serial No. 10/063,557. As stated in paragraph 5 of the declaration, "Those who work in this field are well aware that in the vast majority of cases, when a gene is over-expressed...the gene product or polypeptide will also be over-expressed.... "

Further, "the detection of increased mRNA expression is expected to result in increased polypeptide expression, and the detection of decreased mRNA expression is expected to result in decreased polypeptide expression. The detection of increased or decreased polypeptide expression can be used for cancer diagnosis and treatment." The references cited in the declaration and submitted herewith support this statement.

Applicants also submit herewith a copy of the declaration of Paul Polakis, Ph.D. (attached as Exhibit 3), an expert in the field of cancer biology, originally submitted in a related and co-owned patent application Serial No. 10/032,996. As stated in paragraph 6 of his declaration:

> Based on my own experience accumulated in more than 20 years of research, including the data discussed in paragraphs 4 and 5 above [showing a positive correlation between mRNA levels and encoded protein levels in the vast majority of cases] and my knowledge of the relevant scientific literature, it is my considered scientific opinion that for human genes, an increased level of mRNA in a tumor cell relative to a normal cell typically correlates to a similar increase in abundance of the encoded protein in the tumor cell relative to the normal cell. In fact, *it remains a central dogma in molecular biology that increased mRNA levels are predictive of corresponding increased levels of the encoded protein.* (Emphasis added).

Dr. Polakis acknowledges that there are published cases where such a correlation does not exist, but states that it is his opinion that "such reports are exceptions to the commonly understood general rule that increased mRNA levels are predictive of corresponding increased levels of the encoded protein." (Polakis Declaration, paragraph 6).

The relationship between gene copy number and mRNA levels is discussed in the following references. Orntoft *et al.* (*Molecular and Cellular Proteomics*, 1:37-45 (2002)) (submitted herewith as Exhibit 4) studied transcript levels of 5600 genes in malignant bladder cancers which were linked to a gain/loss of chromosomal material using an array-based method. Orntoft *et al.* showed that there was a gene dosage effect and teach that "in general (18 of 23 cases) chromosomal areas with more than 2-fold gain of DNA showed a corresponding increase in mRNA transcripts" (Orntoft at 37, column 1, abstract). In addition, Hyman *et al.* (*Cancer Research*, 62:6240-6245 (2002)) (submitted herewith as Exhibit 5) used CGH analysis and cDNA microarrays to compare DNA copy numbers and mRNA expression of over 12,000 genes in breast cancer tumors and cell lines. They showed that there is "evidence of a prominent global

influence of copy number changes on gene expression levels" (Hyman at 6244, column 1, last paragraph).

Additional supportive teachings are also provided by Pollack *et al.* (*PNAS*, 99:12963-12968 (2002)) (submitted herewith as Exhibit 6) who studied a series of primary human breast tumors and found that "[b]y analyzing mRNA levels in parallel, we have also discovered that *changes in DNA copy number have a large, pervasive, direct effect on global gene expression patterns* in both breast cancer cell lines and tumors." (Pollack at 12967 at column 1, emphasis added). Their study found that "62% of highly amplified genes show moderately or highly elevated expression, that DNA copy number influences gene expression across a wide range of DNA copy number alterations (deletion, low-, mid- and high-level amplification), that on average, a 2-fold change in DNA copy number is associated with a corresponding 1.5-fold change in mRNA levels." (Pollack at 12963, column 1, abstract). This report is particularly persuasive because the high-resolution comparative genomic hybridization analysis used to assess DNA copy number was particularly sensitive.

Together, the declarations of Mr. Grimaldi and Dr. Polakis and the references cited above establish that the accepted understanding in the art is that there is a direct correlation between the level of mRNA and the level of the encoded protein. Accordingly, Applicants submit that they have established that it is more likely than not that one of skill in the art would believe that because the PRO1027 mRNA is expressed at a higher level in melanoma compared to normal skin, the PRO1027 polypeptide will also be expressed at a higher level in melanoma compared to normal skin. One of skill in the art would recognize that a protein which is differentially expressed in certain cancer cells compared to the corresponding normal tissue would have utility as a diagnostic or therapeutic tool. Thus, Applicants submit that they have established that it is more likely than not that one of skill in the art would recognize the asserted utility of the PRO1027 polypeptide as a cancer diagnostic or therapeutic tool.

The Claimed Polypeptides would have Diagnostic Utility even if there is no Direct Correlation between Gene Expression and Protein Expression

Even assuming *arguendo* that, there is no direct correlation between gene expression and protein expression for PRO1027, which Applicants submit is not true, a polypeptide encoded by

a gene that is differentially expressed in cancer would **still** have a credible, specific and substantial utility.

In paragraph 6 of the Grimaldi Declaration, Exhibit 2, Mr. Grimaldi explains that:

> However, even in the rare case where the protein expression does not correlate with the mRNA expression, this still provides significant information useful for cancer diagnosis and treatment. For example, if over- or under-expression of a gene product does not correlate with over- or under-expression of mRNA in certain tumor types but does so in others, then identification of both gene expression and protein expression enables more accurate tumor classification and hence better determination of suitable therapy.

This conclusion is echoed in the Declaration of Avi Ashkenazi, Ph.D. (attached as Exhibit 7), an expert in the field of cancer biology. This declaration was previously submitted in connection with co-pending application Serial No. 09/903,925. Applicants submit that simultaneous testing of gene expression and gene product expression enables more accurate tumor classification, even if there is no positive correlation between the two. This leads to better determination of a suitable therapy.

This is further supported by the teachings in the article by Hanna and Mornin (attached as Exhibit 8). The article teaches that the HER-2/neu gene has been shown to be amplified and/or overexpressed in 10%-30% of invasive breast cancers and in 40-60% of intraductal breast carcinoma. Further, the article teaches that diagnosis of breast cancer includes testing both the amplification of the HER-2/neu gene (by FISH) as well as the overexpression of the HER-2/neu gene product (by IHC). Even when the protein is not overexpressed, the assay relying on both tests leads to a more accurate classification of the cancer and a more effective treatment of it.

The Applicants have established that it is the general, accepted understanding in the art that there is a positive correlation between gene expression and protein expression. However, even when this is not the case, a polypeptide encoded by a gene that is differentially expressed in cancer would still have utility. Thus, Applicants have demonstrated another basis for supporting the asserted utility for the claimed polypeptides.

Specific Utility

The Asserted Substantial Utilities are Specific to the Claimed Polypeptides

Applicants next address the PTO's assertions that there is no disclosure of any disease or condition in any way related to the claimed polypeptide nor is there disclosure of any diagnostic

assay or analytical assay that could be performed using the claimed polypeptides. The Examiner also asserts that numerous other uses of the claimed polypeptides provided in the specification are insufficient to provide a specific, substantial and credible utility. Applicants respectfully disagree.

Specific Utility is defined as utility which is "specific to the subject matter claimed," in contrast to "a general utility that would be applicable to the broad class of the invention." M.P.E.P. § 2107.01 I. Applicants submit that the evidence of differential expression of the PRO1027 gene in certain types of cancer cells, along with the declarations discussed above, provide a specific utility for the claimed polypeptides.

As discussed above, there are significant data which show that the gene encoding the PRO1027 polypeptide is more highly expressed in melanoma compared to normal skin. These data are strong evidence that the PRO1027 polypeptide is associated with melanoma. Thus, contrary to the assertions of the PTO, Applicants submit that they have provided evidence associating the PRO1027 polypeptide with a specific disease. This is a specific utility – it is not a general utility that would apply to the broad class of polypeptides.

Conclusion

Applicants maintain that the claimed polypeptides meet the requirements of 35 U.S.C. §101. Applicants provide a declaration stating that the data in Example 18 reporting higher expression of the PRO1027 gene in melanoma compared to normal skin are real and significant. This declaration also indicates that given the relative difference in expression levels, the claimed polypeptides have utility as cancer diagnostic or therapeutic tools.

Applicants have also presented the declarations of two experts in the field along with supporting references which establish that the general, accepted view of those of skill in the art is that there is a direct correlation between mRNA levels and the encoded protein levels. Thus, one of skill in the art would find that it is more likely than not that the claimed polypeptide has utility as a diagnostic or therapeutic tool for cancer.

Applicants have also presented the declarations of two experts in the field, along with supporting references, which establish that even in the anomalous case where there is no positive correlation between gene expression and expression of the encoded protein, the simultaneous monitoring of both is useful for diagnosis and further classification of the cancer.

In addition, Applicants have pointed out that the substantial utilities described above are specific to the claimed polypeptides because PRO1027 is differentially expressed in certain cancer tissue compared to the corresponding normal tissue. This is not a general utility that would apply to the broad class of polypeptides.

The use of the PRO polypeptides to generate antibodies is disclosed in the specification at Paragraph [0361]-Paragraph [0396] and Paragraph [0493]-Paragraph [0499]. The use of antibodies against the PRO polypeptides as diagnostic tools is disclosed in the specification in Paragraph [0407].

The utility guidelines recognize that the diagnosis of cancer is a credible utility. (See page 5 of the Revised Interim Utility Guidelines Training Materials which provide that use as a diagnostic marker is a credible utility.)

Furthermore, the utility of the claimed polypeptides as a melanoma diagnostic is specific to the claimed polypeptides and is not a characteristic of polypeptides in general.

Finally, melanoma diagnosis is a substantial utility. (See the caveat in Example 12 of the Revised Interim Utility Guidelines Training Materials, pages 69-70, which states that the utility requirement is satisfied where a protein is expressed in melanoma cells but not on normal skin cells and antibodies against the protein can be used to diagnosis cancer.)

Thus, given the totality of the evidence provided, Applicants submit that they have established a substantial, specific, and credible utility for the claimed polypeptides as a diagnostic or therapeutic agent. According to the PTO Utility Examination Guidelines (2001), irrefutable proof of a claimed utility is not required. Rather, a specific, substantial, and credible utility requires only a "reasonable" confirmation of a real world context of use. Applicants submit that they have established that it is more likely than not that one of skill in the art would reasonably accept the utility for the claimed polypeptides set forth in the specification. In view of the above, Applicants respectfully request that the PTO reconsider and withdraw the utility rejection under 35 U.S.C. §101.

Rejections Under 35 U.S.C. §112, first paragraph

Claims 1-13 were rejected on the assertion that one skilled in the art would not know how to use the claimed invention because the claimed polypeptides lack utility. For the reasons set

forth above, Applicants maintain that the claimed polypeptides possess the utility necessary meet the requirements of 35 U.S.C. §112.

Claims 1-13 were also rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. In particular, the Examiner asserted that the claimed invention encompasses polypeptides with at least 80%, 85%, 90%, 95% or 99% sequence identity to a particular sequence. The Examiner asserts that the claims do not require that the polypeptides possess any particular biological activity, nor any particular conserved structure or other disclosed distinguishing feature.

Applicants have amended the claims to recite that the claimed polypeptides are more highly expressed in melanoma compared to normal skin or are encoded by a polynucleotide that is over-expressed in melanoma compared to normal skin. Applicants maintain that the foregoing limitations provide sufficient distinguishing identifying characteristics of the genus to satisfy the requirements of the first paragraph of 35 U.S.C. §112.

The Examiner asserts that the claims define the genus in relation to "the extracellular domain" or the protein's "associated signal sequence" but that these domains are not set forth in the specification. Applicants note that Figure 56 provides that SEQ ID NO: 56 contains a signal sequence at amino acids 1-33. Applicants have deleted references to "the extracellular domain." Accordingly, Applicants maintain that these amendments render the rejections moot.

The Examiner also rejected Claims 1-13 on the assertion that the biological deposit is necessary to enable the claimed invention and that the Applicants have not stated that the deposit will be maintained for a term of at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository. Applicants do not concede that the biological deposit is necessary to enable the claimed invention, as the sequences of the claimed polypeptides are provided in the Sequence Listing filed along with the application. Nevertheless, Applicants have amended the specification to specify that the deposit will be maintained for a term of at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-13 were rejected as being indefinite in the recitation of the "extracellular domain." Applicants have deleted this terminology from the claims.

Claims 1-13 were also rejected as being indefinite in the recitation of "extracellular domain... lacking its associated signal sequence" and in the recitation that the polypeptide "lacks its associated signal peptide." Applicants maintain that the amendments herein render these rejections moot.

Claims reciting the "associated signal peptide" were also rejected as being indefinite. As discussed above, Figure 56 provides that a signal peptide is located at amino acids 1-33.

Claims reciting "a heterologous polypeptide" or a "chimeric polypeptide" were rejected on the assertion that they are indefinite because the polypeptide has not been described. Applicants maintain that the heterologous polypeptide or chimeric polypeptide comprises the polypeptides of Claim 1 fused to any desired heterologous polypeptide. Those skilled in the art appreciate that any desired chimeric protein can be generated by joining a nucleic acid encoding the polypeptides of Claim 1 in frame with a nucleic acid encoding any desired polypeptide. It is not necessary for applicant to limit the claims to a particular heterologous polypeptide to which the polypeptides of Claim 1 is joined because those skilled in the art appreciate that any desired fusion protein can be generated using standard methodology.

The remaining claims were rejected as being dependent from indefinite claims. However, for the reasons provided above, Applicants maintain that the claims satisfy the requirements of 35 U.S.C. §112. In view of the foregoing, Applicants respectfully request that the rejection under the second paragraph of 35 U.S.C. §112 be withdrawn.

Rejections under 35 U.S.C. §102(b)

Claims 1-11 were rejected under 35 U.S.C. §102(b) as being anticipated by Rhodes, S (submitted to EMBL with last sequence update on May 1, 1999) As discussed above, the sequence of SEQ ID NO: 56 was first disclosed in US Provisional Application 60/090444 filed **June 24, 1998**. As the June 24, 1998 date precedes the date of Rhodes, May 1, 1999, Applicants have shown possession of the claimed invention prior to Rhodes.

The well-established "Stempel Doctrine" stands for the proposition that a patent applicant can effectively swear back of and remove a cited prior art reference by showing that he or she

made that portion of the claimed invention that is disclosed in the prior art reference. (*In re Stempel*, 113 USPQ 77 (CCPA 1957)). In other words, a patent applicant need not demonstrate that he or she made the entire claimed invention in order to remove a cited prior art reference. He or she need only demonstrate prior possession of that portion of his or her claimed invention that is disclosed in the prior art reference and nothing more.

The Stempel Doctrine was extended to cases where a reference disclosed the claimed compound but failed to disclose a sufficient utility for it in *In re Moore*, 170 USPQ 260 (CCPA 1971). More specifically, the patent applicant (Moore) claimed a specific chemical compound called PFDC. In support of a rejection of the claim under 35 U.S.C. § 102, the Examiner cited a reference which disclosed the claimed PFDC compound, but did not disclose a utility for that compound. Applicant Moore filed a declaration under 37 C.F.R. § 1.131 demonstrating that he had made the PFDC compound before the effective date of the cited prior art reference, even though he had not yet established a utility for that compound. The lower court found the 131 declaration ineffective to swear back of and remove the cited reference, reasoning that since Moore had not established a utility for the PFDC compound prior to the effective date of the cited prior art reference, he had not yet completed his "invention".

On appeal, however, the CCPA reversed the lower court decision and indicated that the 131 declaration filed by Moore was sufficient to remove the cited reference. The CCPA relied on the established Stempel Doctrine to support its decision, stating:

> An applicant need **not** be required to show [in a declaration under 37 C.F.R. § 1.131] any more acts with regard to the subject matter claimed that can be carried out by one of ordinary skill in the pertinent art following the description contained in the reference....the determination of a practical utility when one is not obvious need **not** have been accomplished prior to the date of a reference unless the reference also teaches how to use the compound it describes. (Id. at 267, emphasis added).

Thus, *In re Moore* confirms the Stempel Doctrine, holding that in order to effectively remove a cited reference with a declaration under 37 C.F.R. § 1.131, an applicant need only show that portion of his or her claimed invention that appears in the cited reference. Moreover, *In re Moore* stands for the proposition that when a cited reference discloses a claimed chemical compound either absent a utility or with a utility that is different from the one appearing in the

claims at issue, a patent applicant can effectively swear back of that reference by simply showing prior possession of the claimed chemical compound. In other words, under this scenario, the patent applicant need not demonstrate that he or she had discovered a patentable utility for the claimed chemical compound prior to the effective date of the prior art reference.

While these cases discuss the ability to effectively swear back of the cited reference by way of a 131 declaration, Applicants submit that the same reasoning applies here, where the application claims priority back to a disclosure that predates the cited reference. Rhodes discloses amino acids 1-77 of SEQ ID NO: 56 and states that the disclosed amino acid sequence is "a hypothetical protein." Applicants demonstrated, by means of the disclosure in their provisional application filed June 24, 1998, that they were in possession of so much of the claimed invention, i.e. SEQ ID NO: 56, as disclosed in the Rhodes reference dated May 1, 1999. Thus, Applicants respectfully submit that the cited reference is not available as prior art, and request that the rejection under 35 USC §102 be withdrawn.

Conclusion

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 30, 2004

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